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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

1001.1869101

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on DECEMBER 22, 2008Signature Typed or printed name THU H. LE-TO

Application Number

10/604,504

Filed

JULY 25, 2003

First Named Inventor

CLARK C. DAVIS

Art Unit

3736

Examiner

BRIAN SCOTT SZMAL

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

 applicant/inventor.

Signature

 assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

J. SCOT WICKHEM

Typed or printed name

 attorney or agent of record.Registration number 41376612.677.9050

Telephone number

 attorney or agent acting under 37 CFR 1.34.Registration number if acting under 37 CFR 1.34 12-22-2008

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.



*Total of _____ forms are submitted.

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P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

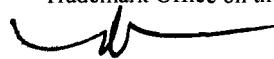
Applicant: CLARK C. DAVIS et al. Confirmation No.: 1503
Serial No.: 10/604,504 Examiner: BRIAN S. SZMAL
Filed: JULY 25, 2003 Group Art Unit: 3736
Docket No.: 1001.1869101 Customer No.: 28075
Title: MEDICAL DEVICE FOR NAVIGATION THROUGH ANATOMY AND
METHOD OF MAKING SAME

PRE-APPEAL CONFERENCE BRIEF

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Thu H. Le-To

DECEMBER 22, 2008

Date

Dear Sirs:

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 25, 27, 53, 55, 58, 59, and 82-87 are rejected under 35 U.S.C. §103(a) as being unpatentable over Jacobsen et al. in U.S. Patent No. 6,579,246 in view of Shiber in U.S. Patent No. 5,135,531, as evidenced by Hernandez et al. in U.S. Patent No. 5,396,212.

Applicants respectfully submit that this rejection is a clear error.

In the Final Office Action mailed October 6, 2008, the Examiner indicated that:

- a) "Jacobsen et al, however fail to disclose the coil being formed from a wire having a substantially non-circular cross section ...",
- b) "Shiber discloses a guided atherectomy system and further discloses the coil being formed from a wire having a substantially non-circular cross section ...", and
- c) "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guidewire coil of Jacobsen et al to include the use of a

non-circular cross section, as per the teachings of Shiber, since the substitution of a non-circular cross-section coil in the place of a circular cross-section coil would provide the predictable result of being able to navigate a guidewire through the vasculature of the patient.” (emphasis added).

In stating this rejection, the Examiner appears to be relying on Exemplary Rationale B listed in MPEP §2143. The Examiner confirmed that this rationale is being relied upon during the telephone interview with Applicants’ representative on November 13, 2008.

Exemplary rationale B indicates that the “[s]imple substitution of one known element for another to obtain predictable results” may support a conclusion of obviousness. This rationale is derived from *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ 2d 1385, 1395-97 (2007).

The Examiner is not *substituting* the coil in Jacobsen et al. with the coil from Shiber but rather is *modifying* the coil in Jacobsen et al. so that it has the shape of the coil in Shiber. Accordingly, this combination does not fall under the “MPEP §2143 KSR-derived Rationale B” because it is not a *substitution* of one structure for another but rather it is a *modification* of the coil in Jacobsen et al. according to the teachings of Shiber. Because of this, the obviousness analysis should not be based on the “MPEP §2143 KSR-derived Rationale B”, as utilized by the Examiner. Because the Examiner maintains that *KSR* applies, the rejection represents a clear error.

Because “MPEP §2143 KSR-derived Rationale B” does not apply, in order to sustain the rejection the Examiner must either provide another applicable “MPEP §2143 KSR-derived Rationale” or support a *prima facie* rejection based on another applicable portion of the MPEP. Because the Examiner has failed to do so, the rejection represents a clear error.

MPEP §2143.01 states that in order to establish a *prima facie* case of obviousness there must be some motivation to combine the references. As previously stated, there is no reasonable motivation for combining the cited art. For example, Shiber appears to teach the helical coil for improving the atherectomy device by providing a means for coring through an obstruction and providing a barrier for the cored material, to prevent the cored material from freely rotating around the guidewire. Applicants fail to understand why one of ordinary skill in the art would be motivated to utilize the shape of a coring helical coil in Shiber in the coil

of Jacobsen et al. as nothing in the cited art teaches or suggests such a combination. In other words, why would one of ordinary skill in the guidewire art, looking for a way to improve a radiopaque coil, turn to a coring atherectomy device for inspiration?

Because there is no motivation to combine the references, Applicants respectfully submit that the rejection is a clear error.

Turning back now to the rejection as stated by the Examiner, even if it is assumed that “MPEP §2143 KSR-derived Rationale B” *could* apply, Applicants still maintain that the rejection represents a clear error.

As previously indicated, the Supreme Court stated in *KSR* that:

[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

See page 14 of the April 30, 2007 slip opinion. The Court went on to state:

[i]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Emphasis added; see page 15 of the April 30, 2007 Slip Opinion. Finally, in quoting *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006), the Court stated:

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

Emphasis added; see page 14 of the April 30, 2007 Slip Opinion. The Court made clear that an obviousness rejection requires some articulated reason of why one skilled in the art would have been prompted to combine the elements on the claimed manner. Applicants respectfully submit that the Examiner has failed to do so. Instead, the Examiner merely indicated that “[i]t would have been obvious ... to modify the guidewire coil of Jacobsen et al to include the use of a non-circular cross section, as per the teachings of Shiber, since the substitution of a non-circular cross-section coil in the place of a circular cross-section coil would provide the predictable result of being able to navigate a guidewire through the vasculature of the

patient.” This statement does not express an articulated reason why the modification would be desirable based on the art but rather it indicates that, according to the Examiner, such a substitution *may have* a predictable result. This fails to meet the standard outlined by the Court and, thus, represents a clear error.

Furthermore, in maintaining that *KSR* allows for the simple substitution of one structure for another, we believe that the Examiner has extended the holding of *KSR* well beyond what the United States Supreme Court ruled. In speaking about how simple substitution generally does not produce a non-obvious invention, the Supreme Court reminded us in *KSR* of how for nearly 60 years that:

a ‘patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdrawn what is already known in the field of its monopoly and diminishes the resources available to skillful men.’

KSR Int'l Co. v. Teleflex Inc., (550 U.S. __ 2007), page 12 of the April 30, 2007 slip opinion quoting *Great Atlantic and Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 (1950). Based on this well established principle, substituting a screw for a nail is not likely to yield a non-obvious invention. The Supreme Court did not reverse this standard in *KSR* and it remains the law today.

When assessing obviousness, one must not lose track of the governing standard articulated by the Court – namely, that uniting old objects without a change in function (e.g., substituting one known element like a nail for another such as a screw) is likely to be obvious. Turning now to the instant application, the Examiner is attempting to substitute an auger shaped coring wire on an atherectomy system (which is designed to bore through an obstruction in a vessel) for a radiopaque coil (which is designed to aid in visualization of the device). This is not merely the uniting of old elements without a change in their respective functions (e.g., like substituting a nail for a screw) but rather a completely redesigned device that is created without regard to the function of the elements at all. Not only does this substitution fail to be obvious, the art strongly supports the notion that such a substitution would be non-obvious under the Supreme Court’s well-established rules.

Finally, the claims require that the coil be both radiopaque and be disposed within the tubular member. The coil in Shiber is neither radiopaque nor disposed within another tube. Thus, even if the coil in Shiber was substituted for the coil of Jacobsen et al., the resultant device would fail to meet the claimed invention. Indeed, if the coil in Shiber was disposed within a tube, such an arrangement would render the Shiber device unsatisfactory for its intended purpose as it would no longer perform the intended coring function. This also fails to support a conclusion of obviousness. See: MPEP §2143.01-V.

For at least the reasons set forth above, Applicants respectfully submit that this rejection is a clear error and should be withdrawn in due course.

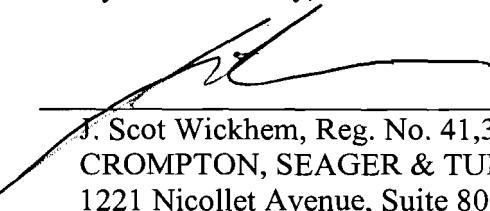
Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Jacobsen et al. in view of Shiber, as evidenced by Hernandez et al. in view of Levine et al. in U.S. Patent Application Publication No. 2003/0009157 or over Jacobsen et al. in view of Shiber, as evidenced by Hernandez et al. in view of Boyle et al. in U.S. Patent Application Publication No. 2003/0105484. Applicants respectfully submit that for similar reasons to those set forth above (and additionally for the reasons set forth in reply filed July 21, 2008), this rejection is a clear error.

Reexamination and reconsideration are requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
CLARK C. DAVIS et al.

By their Attorney,

Date: 12-22-08


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